FEB 1 2 2003

510(k) SUMMARY
Olympus Ultrasonic Surgical System

K021962

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Manufacturer of the subject device

Name & Address of Manufacturer ;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku, Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	8010047
Address, Phone and Fax Number of R&D Department Endoscope Division	12951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5101 FAX 81-426-46-2786

2 Name of Contact Person

Name :	Ms. Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc.
Address, Phone and Fax	Two Corporate Center Drive Melville, NY 11747-3157 Japan TEL (631)844-5688 FAX (631)844-5416

B. Device Name, Common Name

1. Device Name :	Olympus Ultrasonic Surgical System
2. Common/Usual Name :	Ultrasonic Surgical System
3. Classification Name :	Class II Instrument, Ultrasonic Surgical LFL

C. Predicate Devices :

#K002981 Harmonic Scalpel
#K972114 Olympus SonoSurg Scissors Set T3000
#K990430 Hand piece
#K972114 Olympus Transducer MAJ-336
#K000095 SonoSurg Generator Set SonoSurg-G2 Set

D. Summary Description of the Device

1. Summary

The Olympus Ultrasonic Surgical System is composed of three sections, (1), (2), and (3).

(1) Olympus SonoSurg Scissors 5mm O.D. T3050" or "Olympus SonoSurg Long Hook 5mm O.D. T3060" or "Olympus SonoSurg Long Scissors 5mm O.D. T3070", or "Olympus SonoSurg Scissors 5mm O.D., HF Series.
(2) Olympus SonoSurg Transducer SonoSurg-T2H.
(3) Olympus SonoSurg Generator Set SonoSurg-G2 Set (SonoSurg-G2, MAJ-51).

This device is intended to cut and coagulate soft tissue for obstetric/ gynecologic surgery, and for open and laparoscopic surgery.

2. Design

"Olympus Ultrasonic Surgical System" has been designed, manufactured and tested in compliance with Voluntary Safety Standards. It meets the requirements of IEC 60601-1, IEC60601-1-1,IEC60601-1-2.

3. Materials

There are no new patient-contacting materials.

E. Intended Use of the device

Olympus Ultrasonic Surgical System has been designed to be used with the Olympus SonoSurg Generator Set (SonoSurg-G2 Set) and an electrosurgical unit to cut and coagulate soft tissue for open and endoscopic procedures in general surgery. Also it has been designed to be used with them to cut and coagulate soft tissue for obstetric/gynecologic surgery, and for open and laparoscopic surgery.

F. Technological Characteristics

Theory of the operation of "Olympus Ultrasonic Surgical System" is that the electrical energy employed in the "Olympus SonoSurg-G2" is changed to mechanical energy by ultrasonic vibration in the "Olympus SonoSurg Transducer SonoSurg-T2H". Therefore, this system can cut and coagulate body tissue by ultrasonic vibration. This system is the same as the Predicate Devices which include, "Olympus SonoSurg Scissors Set T3000(#K972114)", "Olympus Transducer MAJ-336 (#K972114)" and "Olympus SonSurg-G2 (#K000095)".

G. Reason for not requiring clinical data

When compared to the predicate devices, "Olympus Ultrasonic Surgical System" does not incorporate any significant changes that would effect safety or efficacy. Therefore clinical data is not necessary for its evaluation of safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2003

The Olympus Optical Company
Tina Steffanie-Oak
Senior Regulatory Affairs Specialist
2 Corporate Center Drive
Melville, New York 11747

Re: K021962
Trade/Device Name: Olympus Ultrasonic Surgical System
Regulation Name: Ultrasonic surgical system
Regulatory Class: Unclassified
Product Code: LFL
Dated: November 8, 2002
Received: November 18, 2002

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OLYMPUS

Indications for Use Statement

510(k) Number(if known): ~~Not assigned yet.~~ K0 21962

Device Name: Olympus Ultrasonic Surgical System

Indications for Use :

OLYMPUS Ultrasonic Surgical System has been designed to be used with the Olympus SonoSurg Generator Set (SonoSurg-G2 Set) and an electrosurgical unit to cut and coagulate soft tissue for open and endoscopic procedures in general surgery. Also it has been designed to be used with them to cut and coagulate soft tissue for obstetric/gynecologic surgery, and for open and laparoscopic surgery.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021962

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Prescription 21 CFR 801.109)